

Loughborough University The Centre for Biological Engineering		Acquisition and Receipt of Biological Materials		
Doc Ref: FS008.1 : HTA-PR-FORM/007	Version N°:	1.0	Issue Date:	

ARF No: CBE/ARF/00049

<b>PART A: To be completed by the Receiver (a separate form must be completed for each sample type)</b>				
<b>A1. Details of Sample/Specimen</b>				
Type/ID: (eg primary cell, cell line, tissue, body fluid, excreta, biological agent)	Primary human peripheral blood CD4+ T cells			<input checked="" type="checkbox"/> Human <input type="checkbox"/> Animal
Format / Quantity: (eg vials, slides, etc)	1.5x10 <sup>7</sup> cells in 1 vial (in 1ml Cryostor CS10 freezing media)			
Tissue site/Organ source:	Peripheral blood			<input type="checkbox"/> N/A
Batch N°:				
Is the sample/specimen considered to be Relevant Material under the Human Tissue Act (HTA)? If No, go to section A2.				<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Is the material obtained from an HTA licenced Tissue Bank with REC approval for generic research use?				<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Is the material obtained for storage and use under a project specific NHS REC approval?				<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Is the material licensable under the HTA? Indicate source below:				<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<input type="checkbox"/> HTA licensed organisation <input checked="" type="checkbox"/> Commercial Supplier <input checked="" type="checkbox"/> Imported (from outside England, Wales or N.Ireland)				
If Yes, list lot numbers (or other identifier) & the corresponding assigned unique sample ID	Lot N°: 19068130C	Assigned Unique ID (Procuro): S00204432		
If Yes, provide Project Ref N°:	CBE BRA 198; CBE BRA 183			
If Yes, provide the name of the PI:	Dr Karen Coopman			
<b>A2. Details of Receipt</b>				
Date/Time of receipt	Date	12/04/21	Time:	10am
ID of Receiver	Name:	Nishant Joglekar	Dept:	Chemical Engineering
ID of Supplier/Provider	Name:	StemCell Technologies	Country:	United States
<b>PART B: To be completed by the Receiver</b>				
<b>B1. Inspection and Quarantine</b>				
Has a biological risk assessment for the use of this material been approved?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Ref Number: CBE BRA 198		
Physical integrity of the material(s) acceptable?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	If No, describe action taken		
Quantity received correct?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	If No, describe action taken		
Labelling correct and legible?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	If No, describe action taken		
Is the relevant documentation attached to this form?  If No, add reference or details to ensure traceability	C of A or equivalent evidence of quality	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A		
	Agreements to enable transfer of material eg MTA, SLA	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A		
	Details/evidence/assurance of consent	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A Evidence of consent in email - seen by dQM		

	Other (describe)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
Temporary storage - Quarantine location (as applicable)	Building/Room	H30, Centre for Biological Engineering
	Storage Unit ID	Bank 7 (S00204432)
	Within storage unit location ID	Rack 5/Box B/01
	Date/Time of quarantine	12/04/21; 10.30am
Submitted by:	Signature: <i>Nishant Jogalekar</i>	Date: 12/04/21

**PART C: To be completed by the departmental Quality Manager**

**C1. Quality Assurance Checks**

Has the sample/specimen been screened for infectious biological agents?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Has the donor been screened for infectious biological agents?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Has the sample/specimen been screened and tested negative for mycoplasma?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
Is there evidence that the supplier/provider operates under national or international standards or other recognised certification?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
For HTA licensable material, is there sufficient evidence to support the requirements for storage and use of the material under the University's HTA Research Licence?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Is there sufficient evidence to support the requirements for HTA licensing exemption?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

**C2. Approval for release from quarantine**

Can the material be released from quarantine and transferred to designated storage area or released for processing?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
If No, provide recommendations for deposition of the material and the results of any action relating to non-conforming material.	<input type="checkbox"/> Accept as is, but with extra controls	
	<input type="checkbox"/> Rework or reprocess to meet the specified requirements	
	<input type="checkbox"/> Test to meet specified requirements	
	<input type="checkbox"/> Return to supplier/provider	
	<input type="checkbox"/> Disposal.	
If Yes, provide details of storage location (as applicable)	Building/Room	
	Storage Unit ID	
	Within storage unit location ID	AS Above
	Database Reference	
	Date/Time of transfer	
Approved by:	Signature: <i>cmj</i>	Date: 12/4/21